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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Cy A. Stein et al.

Serial No. : 10/002,884 Examiner: J. Schultz

Filed : November 2, 2001 Group Art Unit:1635

For : PEPTIDES THAT DELIVER ANTISENSE OLIGONUCLEOTIDES WHICH DOWNREGULATE PROTEIN EXPRESSION IN CELLS

1185 Avenue of the Americas
New York, New York 10036
January 5, 2004

Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION IN RESPONSE TO DECEMBER 4, 2003 OFFICE ACTION

This Communication is being submitted in response to a December 4, 2003 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the December 4, 2003 Office Action is due January 4, 2004. However, since January 4, 2004 falls on a Sunday, a response which is filed on the next succeeding day which is not a Saturday, Sunday, or Federal Holiday, i.e. Monday, January 5, 2004, is considered timely filed under 37 C.F.R. 1.7. Accordingly, this Communication is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

In the December 4, 2003 Office Action, the Examiner stated that restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 22, 24-32, and 34-39, drawn to the molecular

complex comprising the polypeptide of SEQ ID NO: 2 and the oligonucleotide of SEQ ID NO: 5, including methods of making and using said compound and pharmaceutical composition thereof.

II. Group 2, claims 1-10, 23, 24-32, and 34-39, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 2 and the oligonucleotide of SEQ ID NO: 6, including methods of making and using said compound and pharmaceutical compositions thereof.

III. Claims 11-22, 24-31, and 33-39, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 1 and the oligonucleotides of SEQ ID NO: 5, including methods of making and using compound and pharmaceutical compositions thereof.

IV. Claims 11-21, 23-31, and 33-39, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 1 and the oligonucleotide of SEQ ID NO: 6, including methods of making and using said compound and pharmaceutical compositions thereof.

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of Examiner's Group I, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 2 and the oligonucleotides of SEQ ID NO: 5.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction requirement be withdrawn in view of the fact that the claims of Groups I-IV are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect...". The claims of Group I-IV are related in that they are drawn to similar compounds, compositions, and methods of use. All of the methods relate to peptide delivery of antisense to cells.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the

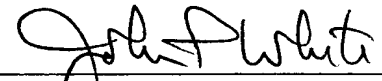
Examiner if restriction were not required. A search of prior art with regard to any of Groups I-IV would necessarily identify art for the other Groups. Since there is no serious burden on the Examiner to examine Groups I-IV in the subject application, the Examiner must examine the entire application on the merits. More specifically, applicants maintain that a search of prior art with regard to Group I or III would necessarily identify art for Group II or IV respectively, as the transporting peptide component is the same in Groups I and II and in Groups III and IV.

Applicants maintain that claims 1-39 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-39 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. If any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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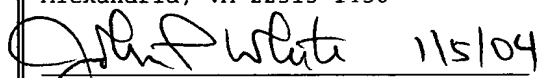

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John P. White — Date
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